

EXHIBIT D



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September 26, 2006

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BY FEDERAL EXPRESS

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Dept. of Health and Human Services
200 Independence Ave., S.W., Suite 314G
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Daniel Meron, Esq.
General Counsel
Office of the General Counsel
U.S. Dept. of Health and Human Services
330 Independence Ave., S.W., Suite 722A
Washington, DC 20201

Re: *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456, D. Mass.
Civil Action No. 01-12257-PBS, Judge Patti B. Saris

Dear Dr. McClellan:

I write on behalf of Track 1 Defendants ("Defendants") in the above-referenced litigation regarding our intent to request the testimony of one or more former CMS employees – Nancy-Ann Min DeParle, Thomas A. Scully, and Stanley Weintraub – at a trial in the District of Massachusetts beginning on November 6, 2006. The trial concerns the so-called Average Wholesale Price for drugs reimbursed under Medicare Part B, and will proceed before Judge Patti B. Saris.

As an initial matter, we believe that the relevant *Touhy* regulation – 45 C.F.R. § 2.4 – is inapplicable because the United States is a party to the action.¹ The Justice Department disagrees,² and we are proceeding under the regulation to avoid an unnecessary dispute. However, given that the trial is less than two months away, we respectfully ask that you make a decision by October 15, 2006, and that you notify us a week from now, October 3, 2006, whether

¹ As I have expressed in prior correspondence with counsel for the United States in this action, (*see* Ltr. from John T. Montgomery to Gejaa T. Gobena and George B. Henderson, II (Aug. 31, 2006), attached hereto as Ex. 1), it is Defendant's position that 45 C.F.R. § 2.1(1) exempts any request for Mr. Scully's testimony from the *Touhy* regulations, as this is a civil proceeding in which the United States is a party. The same reasoning applies to Ms. DeParle and Mr. Weintraub. This letter in no way waives our position.

² The Justice Department insists that the United States is not a party to the case, (*see* Ltr. from George B. Henderson, II (Sept. 12, 2006), attached hereto as Ex. 2), notwithstanding the fact that the Government appears as a "consolidated plaintiff" on the docket, it has moved to appear as an "interested party," it has intervened in a matter transferred to the MDL, and it has filed an *amicus* brief in the instant case.

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you intend to do so. If no commitment is received by that date, we will seek an order from the court compelling a response.

45 C.F.R. § 2.4 provides that any requests for testimony of a former employee of the Department of Health & Human Services ("DHHS") "must state the nature of the requested testimony, why the information sought is unavailable by any other means, and why the testimony would be in the interest of the DHHS or the federal government." Such a request should be granted if it "would promote the objectives of the Department." 45 C.F.R. § 2.3. Such is the case here.

1. Nature of the Requested Testimony

Ms. DeParle, Mr. Scully, and Mr. Weintraub would testify regarding their knowledge of average wholesale price ("AWP") for drugs covered by Medicare Part B during, but not limited to, their tenure at the Center for Medicare & Medicaid Services ("CMS"), formerly Health Care Financing Administration ("HCFA"). Ms. DeParle was the HCFA Administrator and Deputy Administrator from 1997 to 2000, Mr. Scully was the CMS Administrator from 2001 to 2003, and Mr. Weintraub was a Senior Policy Advisor at CMS from 1984 to 1998.

Specifically, Ms. DeParle,³ Mr. Scully,⁴ and Mr. Weintraub would testify to their knowledge or understanding of the use of AWP for reimbursement, the relationship between AWP and provider acquisition costs, the extent to which reimbursement for drug ingredients operated as a cross-subsidy for the inadequate reimbursement of the costs of service and administration, the reasons for maintaining AWP as part of Medicare reimbursement, and the general operation of the reimbursement system. These issues are relevant to the AWP litigation.

2. Availability from Other Means

The information that could be gleaned from the testimony of Ms. DeParle, Mr. Scully, and Mr. Weintraub is unavailable through other means. Ms. DeParle provides a unique perspective as HCFA's Administrator during pivotal years when HCFA tried to reform AWP. On October 1, 1997, for example, Ms. DeParle wrote to the OIG stating that the "published AWP's currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices," and that HCFA is taking steps to remedy the situation, including

³ Ms. DeParle's testimony would provide the basis for her Congressional testimony and other public statements regarding AWP. Examples of such testimony are attached as Exhibit 3.

⁴ Mr. Scully's testimony would provide the basis for his statements which are already in the record and – indeed – have been subject to some dispute between the parties in their summary judgment papers and in arguments before the Court. Examples of Mr. Scully's public statements on AWP are attached as Exhibit 4.

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convening a "[w]orkgroup to develop an electronic file consisting of the AWP," and including a "provision in the President's 1998 budget bill . . . requiring physicians to bill the program the actual acquisition cost for drugs."⁵ On March 13, 2000, Ms. DeParle testified before the House Ways and Means Committee that the AWP in the "Red Book and the Blue Book . . . turns out to be wrong . . . [and is] not what is really the wholesale price."⁶ Ms. DeParle explained that the "President has for the last . . . four or five years now proposed a proposal to help us to be able to do this better," and that the Justice Department is helping HCFA "compil[e] better information about what prices wholesalers are actually paying."⁷ Ms. DeParle's testimony, which would provide the basis for her statements regarding AWP, is unavailable through other means.

Similarly, Mr. Weintraub can offer unique testimony in light of his role in developing and implementing Medicare Part B reimbursement policies from 1984 to 1998 while a Branch Chief and Senior Policy Advisor at HCFA. In addition to his perspective concerning the evolution of the AWP reimbursement methodology over time, Mr. Weintraub played a key role in drafting the 1991 proposed and final rules in the Federal Register setting drug reimbursement at the lower of estimated acquisition cost or AWP, as well as in drafting the Medicare reimbursement provision of the Balanced Budget Act of 1997. He also can testify as to government reports and knowledge regarding AWP. This testimony is unavailable through other means.

Finally, Mr. Scully was the CMS Administrator during the time in which Congress adopted the "average sales price" methodology in the Medicare Modernization Act of 2003. During this time, Mr. Scully developed expertise in the policy and political reasons CMS and Congress retained the use of AWP and, in 2003, finally adopted a new system. He also had access to the kind of government reports at issue in this case, and can testify about government knowledge and decision-making regarding AWP. For example, Mr. Scully testified before the U.S. Senate Finance Committee that he "was involved in this [AWP] issue in 1991, the first time the President Bush 41 Administration tried to fix AWP," and was also "involved with [Congress] in Medicaid drug re-bid issues and lots of other related issues on trying to figure out how the government pays appropriately for prescription drugs for a long time."⁸ His conclusion: "[i]t's very clear that the average wholesale price is seriously flawed."⁹ In fact, Mr. Scully testified in 2001 that "this issue has been around about 10 years and I never heard this thorough a discussion on it, and usually what happens is somebody tries to cut a rate and somebody screams that patients are going to be hurt, which is frequently not the case, and we are legislatively prohibited

⁵ Letter to Inspector General June Gibbs Brown by DeParle as Deputy Administrator of HCFA (Oct. 1, 1997) (Ex. 3).

⁶ Transcript of Testimony before House Ways and Means Committee regarding Medicare and Prescription Drug Coverage (Mar. 13, 2000) (Ex. 3).

⁷ *Id.*

⁸ Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002) (Ex. 4).

⁹ *Id.*

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from fixing it."¹⁰ Mr. Scully's testimony would provide the basis for statements such as these, which are already in the record and have been subject to some dispute between the parties. His testimony is simply unavailable through other means.

3. Interests of DHHS and Federal Government

Allowing Ms. DeParle, Mr. Scully, and Mr. Weintraub to testify is in the best interest of the DHHS, as provided for in 45 C.F.R. § 2.4. One of the stated goals of DHHS is to "protect[] the health of all Americans and provid[e] essential human services, especially for those who are least able to help themselves," and one of the primary functions of CMS is to administer the Medicare program. These class actions are purportedly brought on behalf of participants in the Medicare program – individual Medicare beneficiaries and Medi-Gap insurers – whose claims center around a reimbursement term adopted by CMS and DHHS.

In almost five years of litigation, the parties have disputed the meaning of a term, AWP, used first in a regulation and then in a statute, as well as the extent of the federal government's knowledge regarding AWP. The United States has already taken an active role in this dispute: appearing as a "consolidated plaintiff" on the docket, moving to become an "interested party" in this litigation, and intervening in a similar AWP matter, *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labors., et al.*, now pending before this Court. In this context, Judge Saris, who is presiding over this case, has recognized the potential helpfulness of a government witness to explain the use of AWP as a basis for reimbursement under Medicare Part B. (Tr. of Aug. 3, 2006 Hr'g at 19-20, attached hereto as Ex. 5.). The testimony of Ms. DeParle, Mr. Scully, and Mr. Weintraub, as described *infra*, would be such testimony.

Moreover, the primary justification for denying so-called *Touhy* requests – the conservation of agency resources – is absent in this case. *See, e.g., Moore v. Armour Pharmaceutical Co.*, 927 F.2d 1194, 1197-98 (11th Cir. 1991) (recognizing that requiring *current* DHHS doctors to testify would interfere with the agency's "interest in maximizing the use of its limited resources in dealing with a national health crisis"); *Reynolds Metals Co. v. Crowther*, 572 F. Supp. 288, 290 (D. Mass. 1982) (recognizing that if *current* "OSHA employees were routinely permitted to testify in private civil suits, significant loss of manpower hours would predictably result"). In the instant case, since Ms. DeParle, Mr. Scully, and Mr. Weintraub are *former* employees, the primary reason for denying *Touhy* requests – the conservation of agency resources – does not exist.¹¹

¹⁰ Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 91 (2001) (Ex. 4).

¹¹ In fact, should the agency deny this request, it "may even be more costly to the agency in the long run than allowing the employee to testify when originally requested" due to costs defending the agency decision. Robert R.

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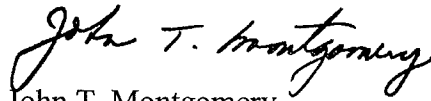
Mark B. McClellan
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For the foregoing reasons, 45 C.F.R. § 2 warrants your authorization to subpoena Ms. DeParle, Mr. Scully, and Mr. Weintraub in the above-referenced litigation. As stated, this matter is scheduled for trial beginning on November 6, 2006, and Judge Saris has expressed interest in hearing testimony from government witnesses. Under the circumstances, we respectfully ask that you notify us as soon as practicable, and no later than one week from today, whether CMS will respond to our letter by October 15, 2006. If you cannot do so by next week, then we will begin preparation of a motion seeking an order compelling a response, and also alert the court to the threshold dispute concerning the applicability of the *Touhy* regulation to this situation. If you have any concerns, we would be pleased to speak with you at your earliest convenience.

Very truly yours,


John T. Montgomery

JTM/tw
Enclosures

cc: Gejaa T. Gobena
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Assistant U.S. Attorney
John J. Moakley U.S. Courthouse
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EXHIBIT 1



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August 31, 2006

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John J. Moakley U.S. Courthouse
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Boston, MA 02110

Re: *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456

Dear Mr. Gobena and Mr. Henderson:

I write on behalf of the Track 1 Defendants in the above-referenced litigation ("Defendants") concerning current or former government employees, particularly of the Center for Medicare and Medicaid Services ("CMS"), who may testify at the upcoming November trial.

You will recall that Judge Saris asked the parties at the hearing on August 3 whether any current or former government employees would be called as witnesses at the trial in November, and if so, she noted that the parties should consider the implications of the so-called *Touhy* regulations. *See* 45 C.F.R. § 2 *et. seq.* These regulations set forth a procedure for notice of the intention to call a former government employee of an agency of the Department of Health and Human Services as a witness and for a response from the head of the relevant agency, in this instance the Administrator of CMS.

We have reviewed the regulations, however, and they are not applicable to this proceeding. The United States appears as a "consolidated plaintiff" on the docket, and it has moved to appear as an "interested party" in MDL No. 1456, a motion which was granted by the Court. Additionally, the United States has intervened in a matter, *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., et al.*, which was recently transferred to MDL No. 1456 and is now pending before this Court. Accordingly, we do not believe the regulations are applicable. *See id.* at 2.1(d)(1).

The Defendants do intend to present one or more current or former employees of CMS as witnesses at trial. Even if the *Touhy* regulations were applicable here, which they are not, it is clear that any testimony from a current or former CMS employee would merit approval from the CMS Administrator. As you know, Judge Saris has expressed her desire to hear from such

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Gejaa T. Gobena
George B. Henderson, II

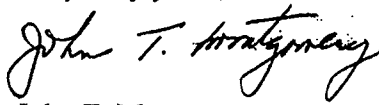
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witnesses regarding the use of AWP as a basis for reimbursement of prescription drugs under Medicare Part B. Certainly, it would "promote the objectives of the Department," as provided in 45 C.F.R. § 2.3, to permit current or former employees of CMS to comply with the Court's request for testimony concerning these issues. The Defendants also believe that the testimony would be relevant to the development of a complete and accurate record on the issues presented for decision

If you would like to discuss the foregoing, we would be please to speak with you at your earliest convenience.

Very truly yours,

A handwritten signature in cursive script, reading "John T. Montgomery".

John T. Montgomery

EXHIBIT 2



U.S. Department of Justice

*United States Attorney
District of Massachusetts*

*Writer's Direct Dial Number:
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*John Joseph Moakley U.S. Courthouse, Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210*

September 12, 2006

John T. Montgomery
Ropes & Gray
One International Place
Boston MA 02110-2624

Re: In re Pharmaceutical Industry Average Wholesale Price Litigation,
MDL No. 1456 (D. Mass.)

Dear Mr. Montgomery:

On behalf of the Department of Health and Human Services (HHS), I am responding to your letter of August 31, 2006, in which you set forth the Track 1 Defendants' position that the HHS Touhy regulations do not apply to the MDL proceedings.

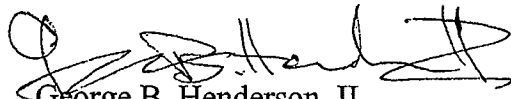
Your position is meritless. The fact that the United States is a plaintiff in a case that has been transferred to MDL No. 1456 does not make the United States a "party" to any of the class action cases, including the Track 1 case scheduled for trial in November. The transfer of the government's case to MDL 1456 was for pretrial purposes only. The United States moved to appear in the MDL as an "interested party" solely to facilitate electronic filing of documents, as the motion indicates. Judge Saris has already indicated her view that the United States is not a party to the Track 1 class action cases and that the Touhy regulations apply. See August 3, 2006, Status Conference Hearing Transcript at 18:15 - 20:2.

If the Track 1 Defendants seek the testimony of a present or former government employee concerning information acquired in the course of performing official duties or because of the person's official relationship with the Department, then the Defendants must comply with the Department's regulations at 45 C.F.R. § 2 et seq. Any request for testimony "must be addressed to the Agency head in writing and must state the nature of the

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requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interest of [HHS] or the federal government." 45 C.F.R. § 2.4.

Sincerely,



George B. Henderson, II
Assistant U.S. Attorney

cc: Gejaa T. Gobena
Carol Bennett

EXHIBIT 3

EXHIBIT 3

NANCY-ANN MIN DePARLE'S STATEMENTS REGARDING AWP

- "The published AWP's currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs." Letter to Inspector General June Gibbs Brown by DeParle as Deputy Administrator of HCFA (Oct. 1, 1997).
- "HCFA convened a Workgroup to develop an electronic file consisting of the AWP's for drugs covered by Medicare. HCFA will then distribute this file to Medicare contractors for their use in paying claims for drugs." Letter to Inspector General June Gibbs Brown by DeParle as Deputy Administrator of HCFA (Oct. 1, 1997).
- "We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways." Letter to Inspector General June Gibbs Brown by DeParle as Deputy Administrator of HCFA (Oct. 1, 1997).
- "Well, what we're trying to do is make sure that Medicare pays a fair price. And we think that the law right now provides that Medicare pays for the drugs that it provides incident to a physician's services. It's supposed to pay 95 percent of the average wholesale price. For that we rely on some industry published data, which . . . [is in] the Red Book and the Blue Book, which turns out to be wrong. It turns out to be not what is really the wholesale price." Transcript of Testimony before House Ways and Means Committee regarding Medicare and Prescription Drug Coverage (Mar. 13, 2000).
- "[T]he President has for the last, I think, four or five years now proposed a proposal to help us to be able to do this better, to make sure that we get the prices that physicians actually are paying. And with that we've said we'd like to make sure that we're paying physicians appropriately for administration of those drugs. That's something that this Committee has raised. But we want to make sure Medicare pays a fair price." Transcript of Testimony before House Ways and Means Committee regarding Medicare and Prescription Drug Coverage (Mar. 13, 2000).
- "REP. DOGGETT: And what you're saying is that there have been I believe four occasions when the administration has come to the Republican Congress and has said, 'Please give us the tools to be sure that the taxpayer's not being ripped off and that they're paying the actual wholesale price, not some contrived' -- MS. DeParle: Inflated price." Transcript of Testimony before House Ways and Means Committee regarding Medicare and Prescription Drug Coverage (Mar. 13, 2000).

- "[T]hrough working with the Department of Justice in its investigations we are compiling a better information about what prices wholesalers are actually paying, and we intend to get that out to our carriers, the private insurance companies that pay Medicare's bills, so that they can start using those prices and reimbursing at that rate. And then we'd still love the opportunity to work with this Committee and with the Congress toward a proposal, like the President's proposal, that we think will do a better job of ensuring that Medicare pays appropriately instead of paying these inflated prices that are not the wholesale price." Transcript of Testimony before House Ways and Means Committee regarding Medicare and Prescription Drug Coverage (Mar. 13, 2000).
- "[T]he agency has plenty of other work to do. Implementing the rest of the MMA could be a full-time job by itself. Dozens of fee-for-service payment changes must be implemented, most through rulemaking, to increase payments for hospitals, physicians, and rural providers. Those are relatively non-controversial and in many cases the implementing regulations and systems changes are well underway. But other changes in the MMA reduce payments, and are both complex and controversial. For example, the MMA changed the payment methodology for the Part B drugs Medicare already covers in 2004, 2005, and 2006. The 2004 change is relatively simple (the payment formula is reduced by 10% to "average wholesale price (AWP) - 15%"), but for 2005 and 2006 the reforms introduce first a new basis for payment, and then a new "competitive acquisition program" that will require rulemaking and extensive interactions with physicians, pharmaceutical companies, and other parties. This is just one example of a complex provision in the MMA that must be implemented alongside the new drug benefit." Testimony before Subcommittee on Oversight of Government Management of Senate Governmental Affairs (Apr. 8, 2004).
- "I remember -- I could be misremembering, but I thought back in 2000 or so there were inspector general reports and maybe other reports that basically said that. So I was very surprised when Zachary's information showed they were using AWP." Public Meeting of the Medicare Payment Advisory Commission (Jan. 16, 2003).
- "As we suggested in May, the right approach to addressing Medicare profits on drugs identified by DOJ is to pay correctly for the drugs, and at the same time make changes, as necessary, to assure that Medicare adequately pays for services related to the provision of the drugs. As we have gathered information on many of the drugs reviewed by DOJ, we have concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate." Letter to Congress 2 (Sept. 8, 2000).
- DeParle also wrote a letter to a Congressman giving the history of Medicare drug reimbursement and the efforts HCFA has taken to reduce reimbursements, such as developing more accurate data on average wholesale prices. Letter to Representative Pete Stark (D-Calif) (May 31, 2000).

EXHIBIT 4

EXHIBIT 4

THOMAS A. SCULLY'S TESTIMONY REGARDING AWP

- "This whole issue, people have been trying to fix this for years. And back to Secretary Shalala and Nancy-Ann DeParle last year, they tried to fix it. Got an outpouring of screaming from every affected party, appropriate or inappropriate, and then were hit with a Congressional prohibition for a year not to look at it." Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 84 (2001).
- "We have been paying more than any other purchaser for Medicare drugs on an outpatient basis for a long time . . . I do think, however, the concern – it is a legitimate concern for the providers – is that if you're going to lower – do we always fix the right price in Medicare, which is what we do for providers? Probably not. Do we have the right price for oncologists and their practice expenses? Probably not." Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 84 (2001).
- "I think this is something the agency has been trying to do for years, and every time it's put its head up, it's got creamed. So we're anxious and excited that many Members of Congress are now aware of it and are interested in fixing it as well." Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 84 (2001).
- "[I]t is clear that the payment system for selected outpatient drugs that are now covered by Medicare is a mess. Medicare now pays more than many other purchasers for the drugs we cover due to the way that drug manufacturers report their prices and Medicare's payment policies. Medicare should pay appropriately for all Medicare benefits, including the drugs we currently cover, and it is unacceptable that the current system results in Medicare paying excessive prices. We also need to pay appropriately for the services required to furnish these drugs." Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 87 (2001).
- "We certainly can pay less on AWP, but if you're trying to find the balance, what I've heard from oncologists and others is, if you're going to cut the AWP, which we rely on, you need to fix the practice expense at the same time and in the same bill. I imagine they wouldn't be very happy to have the drug reimbursement cut at

the same time the practice expenses don't go up." Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 91 (2001).

- "We actually sent out guidance of what we thought was an AWP – not me, but, as you know, Nancy-Ann DeParle and Secretary Shalala – about a year and a half ago to have our carriers interpret what was a low AWP, and there was quite an uproar about that, and the result of it was a legislative prohibition about changing it." Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 91 (2001).
- "[T]his issue has been around about 10 years and I never heard this thorough a discussion on it, and usually what happens is somebody tries to cut a rate and somebody screams that patients are going to be hurt, which is frequently not the case, and we are legislatively prohibited from fixing it." Testimony before Subcommittee on Health and Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. 83, 96 (2001).
- "I was involved in this issue in 1991, the first time the President Bush 41 Administration tried to fix AWP. And I've been involved with you in Medicaid drug re-bid issues and lots of other related issues on trying to figure out how the government pays appropriately for prescription drugs for a long time. It's very clear that the average wholesale price is seriously flawed..." Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002).
- "This issue cries out for legislative solution and I'm glad that you have introduced one. This has been an issue that both the last two administrations have tried to fix. As you well know, in the last administration, Secretary Shalala and Nancy M. DeParle, who's my predecessor and friend, tried to fix this three years ago. And, had an outcry whether appropriate or inappropriate, from virtually every party involved." Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002).
- "But there are a lot of . . . side effects on various providers that are fairly legitimate. If we are going to lower prices for Medicare pays for outpatient drugs, then I think we also need to make appropriate adjustments, probably it's certainly not a one for one swap, it's significantly less than that, but if you can save, whether it's \$800 million or a billion dollars on AWP, I think we probably have to – the GAO said it was about \$50 million, maybe around that area or a little higher, to put back into oncology, probably ESRD clinics, hemophiliac agencies, some DME providers. Many of these providers rely on cross subsidies to survive

basically in the Medicare business." Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002).

- "I think AWP is largely air and a meaningless figure . . . " Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002).
- "[T]he Clinton administration chose to basically send directions out to the contractors just telling them to use a different market level price and that led to a significant backlash that arguably the cross subsidies were disappearing without additional payments to oncologists, hematologists, ESRD clinics, hemophiliac agencies and others." Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002).
- "We collect AMP data for Medicaid on one side of my agency. We have it. WE know what every drug company charges us for Medicaid, what their average manufacturers price is. But, by statute we're not allowed to share that with the Medicare side of the agency. Its' proprietary data just for the purpose of the Medicaid program." Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002).
- "Everybody has acknowledged for years that oncologists have a significant cross subsidy through AWP, so I think there was a subconscious effort . . . to not fully and completely consider all the practice expenses for oncologists because of the acknowledged cross subsidy from AWP's over price. Transcript of Testimony before Finance Committee of U.S. Senate (Mar. 14, 2002).
- "Medicare pays more than many other purchasers for the drugs we cover because of Medicare's payment policies and the way that drug manufacturers report their prices. We all agree that Medicare should pay appropriately for all of Medicare's benefits, including the limited drugs the program currently covers. The current system, which results in Medicare and beneficiaries paying excessive prices for certain prescription drugs, must be fixed. At the same time, we need to be certain that Medicare pays providers appropriately for their services when they furnish drugs to beneficiaries." Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002).
- "Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare drug payments are based, are vastly higher than the amounts drug manufacturers and wholesalers actually charge providers. That means Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers, are spending more than the 'average' price that we believe the law intended them to pay." Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002).
- "Some affected physicians and providers have suggested that they need these Medicare 'drug profits' to cross subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the

administration of chemotherapy for cancer. A better approach is to pay appropriately for both the drugs and the services relating to furnishing these drugs . . ." Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002).

- "The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. Traditionally, AWP has been based on prices reported by drug manufacturers and published in compedia such as the Red Book, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers competitive discounts that reduce the actual amount the physician or provider actually pays for the drugs..." Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002).
- "The Committee, CMS, the Department's Office of the Inspector General (OIG) and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. The IG has published numerous reports showing that true competitive market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the Red Book and other publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions." Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002).
- "In the past, the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid competitively by physicians and providers. However, these efforts have not been successful. For example, the Agency's proposed June 1991 physician fee schedule included payments based on 85 percent of AWP. . . . The Agency received many comments, primarily from oncologists, indicating that an 85 percent standard was inappropriate." Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002) (Ex. 4) at 6.
- "Since the Estimated Acquisition Cost proved to be unworkable, subsequent legislation was proposed that would have required Medicare to pay physicians their actual acquisition cost for drugs. Under this proposal, physicians would tell Medicare what they paid for the drugs and be reimbursed that amount, rather than the Agency developing an estimate of acquisition costs and paying physicians based on that estimate. After considering this proposal, Congress adopted an alternative approach in the Balanced Budget Act of 1997 (BBA), setting Medicare's payment for drugs at the lesser of the billed charge or 95 percent of AWP. While this brought Medicare payments closer to the prices that physicians and providers pay for drugs, Medicare payments were still significantly greater than the competitive discounts obtained by physicians. The system still tied Medicare payments to the artificially inflated industry-reported list prices."

Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002).

- "In 2000, the Agency sent this new information to Medicare carriers and instructed them to consider these alternative wholesale prices as another source of AWP data in determining their January 1, 2001 quarterly update for many of these drugs. However, due to concerns about Medicare reimbursement for the administration of the chemotherapy and clotting factor drugs, the Administration instructed our carriers not to use the data for the drugs at that time." Prepared Testimony before Senate Finance Committee Subcommittee on Health (Mar. 14, 2002).

EXHIBIT 5

1 A P P E A R A N C E S:

2 For the Plaintiffs:

3
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7
8 SHANIN SPECTER, ESQ., and DONALD E. HAVILAND, JR.,
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9
10 For the Defendants:

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1
2 For the United States:

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6 GEORGE B. HENDERSON, ESQ., Assistant United States
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1 P R O C E E D I N G S

2 THE CLERK: In re: Pharmaceutical Industry Average
3 Wholesale Price Litigation, Civil Action No. 01-12257,
4 MDL 1456, will now be heard before this Court. Will counsel
5 please identify themselves for the record August 3, 2006.

6 MR. SOBOL: Good afternoon, your Honor. Tom Sobol
7 for the plaintiffs.

8 THE COURT: Good afternoon.

9 MR. SPECTER: Good afternoon. Shanin Specter,
10 plaintiffs.

11 MR. HAVILAND: Don Haviland, your Honor, for the
12 plaintiffs.

13 MR. BERMAN: Steve Berman, your Honor.

14 MR. EDWARDS: Steve Edwards, BMS.

15 MR. MONTGOMERY: John Montgomery, Schering-Plough
16 and Warrick.

17 MR. WISE: Scott Wise for AstraZeneca, your Honor.

18 MR. CAVANAUGH: Bill Cavanaugh, Johnson & Johnson.

19 MR. DeMARCO: Michael DeMarco, Aventis.

20 MR. MUEHLBERGER: Jim Muehlberger, Aventis.

21 MR. STEMPEL: Scott Stempel, Pfizer and Pharmacia.

22 MR. GOBENA: Your Honor, I would just like to let
23 you know the United States --

24 THE COURT: Has arrived. Actually, why don't you
25 come on up here.

1 MR. GOBENA: All right.

2 THE COURT: And I'm going to ask the USA something
3 ex parte for one second because there's something that was
4 just transferred up here, and I'm not sure --

5 MR. GOBENA: Your Honor, should we identify
6 ourselves for the record?

7 THE COURT: Yes, do that, because I didn't know
8 there were so many of you all.

9 MR. GOBENA: My name is Gejaa Govenia. I'm with the
10 Justice Department.

11 MR. HENDERSON: George Henderson, Assistant U.S.
12 Attorney.

13 MR. BREEN: Jim Breen for the relator Ven-A-Care,
14 the 402s.

15 THE COURT: All right, then we know. All right, I
16 just didn't know if that's public.

17 MR. HENDERSON: It is as a matter of the caption of
18 the case.

19 THE COURT: All right, so why don't at least one of
20 you sit here. The case involving -- you've stepped in and
21 decided to intervene, is that it?

22 MR. GOBENA: That's correct, your Honor.

23 THE COURT: The government has? Are you all
24 familiar with what I'm talking about?

25 MR. MONTGOMERY: Yes, your Honor.

1 MR. CAVANAUGH: Yes.

2 THE COURT: All right, so you get a table to
3 yourself.

4 MR. DALY: Your Honor, just for the record, Jim
5 Daly. I'm here for Abbott Labs, the company that the
6 government intervened with respect to.

7 THE COURT: Okay, thank you very much. I wasn't
8 sure, because I just got notice of it through the MBD docket,
9 whether it was still sealed or not, and that was why I wanted
10 to make sure that I checked that out before I spilled it out
11 in front of this entire room. But it's now public. The
12 Department of Justice is here, right?

13 MR. GOBENA: That's correct, your Honor.

14 THE COURT: All right, so what is your position in
15 general in this case? I haven't had a chance to even go
16 through what the case is about from the Justice Department's
17 point of view.

18 MR. GOBENA: Sure, your Honor. As your Honor has
19 noted, we've intervened in a case that originated in the
20 Southern District of Florida against -- the defendants in the
21 case are Abbott Labs and Hospira as well --

22 THE COURT: And?

23 MR. GOBENA: Hospira, which was a spin-off of
24 Abbott Labs, and what was spun off was the division that
25 manufactured the drugs that were identified in our complaint.

1 THE COURT: Yes, but what's the case? Was it an
2 AWP case?

3 MR. GOBENA: It's a False Claims Act case alleging
4 AWP pricing fraud, so it's the same general subject matter as
5 these cases, but we're bringing it under the False Claims Act
6 as well as we have an unjust enrichment claim and a common
7 law fraud claim as well.

8 THE COURT: And just so I can get a lay of the
9 land -- you may not be prepared to answer this question -- is
10 this just going to be limited to these drugs involving
11 Abbott, or are you going to have a stake in the rest of this
12 litigation?

13 MR. GOBENA: We're really not prepared to answer
14 that question at this time, your Honor, but it's fair to say
15 that there may be additional defendants that enter into our
16 case.

17 THE COURT: All right, thank you. Right now, I
18 thought it would be worthwhile to ask the plaintiffs how much
19 they've accomplished in their notice, since that essentially
20 is the threshold to doing anything, what's been sent out,
21 what hasn't been -- oh, there you are.

22 MR. NOTARGIACOMO: Good afternoon, your Honor. Ed
23 Notargiacomo for the plaintiffs. We are on track with
24 everything your Honor has ordered us to do. On Friday
25 , July 28, we mailed all of the TPP notices.

1 THE COURT: Third-party payor, right.

2 MR. NOTARGIACOMO: Third-party payor notices. The
3 Web site for third-party payors, that version of the Web site
4 went live on Monday, so that as those third-party payors
5 receive the notices, additional information is available.
6 The same thing with the phone bank available to answer
7 third-party payor questions about it as they receive the
8 notices. We are on track with the consumer --

9 THE COURT: So just remind me. Is that just
10 Track 1 third-party payors, or is it Track 2 as well?

11 MR. NOTARGIACOMO: It is just Track 1 third-party
12 payors, your Honor.

13 THE COURT: And just in Massachusetts?

14 MR. NOTARGIACOMO: Well, the third-party payors
15 could be anywhere in the United States.

16 THE COURT: Right, but just with respect to the
17 Massachusetts 93A claim.

18 MR. NOTARGIACOMO: That's right.

19 THE COURT: Yes, I misspoke. All right, so that's
20 going forward just on people who have claims under the
21 Massachusetts statute with respect to third-party payors just
22 for Track 1?

23 MR. NOTARGIACOMO: Yes, your Honor. The notice
24 included notice to third-party payors who would be in Class 2
25 as well as Class 3.

1 THE COURT: All right, so for everyone. I don't
2 have to worry about them again.

3 MR. NOTARGIACOMO: That's correct.

4 THE COURT: What about, when's the opt-out date?
5 What did we end up with?

6 MR. NOTARGIACOMO: I believe October 1, 2006.

7 THE COURT: Now, as I understand it, and I don't
8 know if you all saw this, I got a report from the Department
9 of Health and Human Services yesterday through Mr. Henderson
10 which basically said that, much more polite language, but
11 basically no way are they going to let the notice go in the
12 Medicare bulletin, legalese for "over my dead body." So at
13 this point I think that that is a moot issue. It's too
14 expensive; they don't want it. It's not worth the holdup to
15 litigate the thing. Does anyone feel differently about
16 that?

17 Okay, so we're back with the individualized
18 notice. And, Mr. Henderson, are we on track for that? Have
19 you checked?

20 MR. HENDERSON: I haven't checked recently. I've
21 certainly let the agency know of your order, and I haven't
22 heard anything, anything suggesting that they can't meet it.
23 I can certainly follow up to make sure.

24 THE COURT: Okay, so what I want you to do is every
25 month check.

1 MR. HENDERSON: All right.

2 THE COURT: Because, as you can tell, I'm really
3 moving this at this point, and I'm counting on a Class 1
4 trial in March.

5 MR. HENDERSON: All right, I'll put that on my
6 calendar.

7 THE COURT: You know, just tickler it in every
8 month, write me a little status report just to make sure
9 we're on track because I've got this whole thing triggered to
10 a March date.

11 MR. NOTARGIACOMO: All right.

12 THE COURT: All right, that's great, with respect
13 to Class 1.

14 Now we're dealing with September and November, the
15 two time periods. I've had a chance to briefly read your
16 submissions because I didn't get them till late yesterday,
17 and I was on trial all day today and haven't had a chance to
18 return to them. So the gist of it is, as I understand it,
19 everyone agrees nothing will happen as far as the trial in
20 September. There's a disagreement about November, about
21 whether there should be any proceeding and what it should
22 look like. You want to do Daubert in September.

23 MR. MONTGOMERY: Correct, correct.

24 THE COURT: But I'm just talking about the trial, a
25 basic merits proceeding, which we are going to get to. I'm

1 going to do something in November. I've locked it up, I have
2 staffed up, and that's what we're going to do. So I reject
3 plaintiffs' request to move everything into March. I reject
4 defendants' request to just do knowledge. Knowledge is a
5 piece of it. The plaintiffs have ignored the fact that
6 knowledge is relevant because I have a statute of limitations
7 problem. I've got a discovery rule. At the very least, we
8 have to find out what they knew and when they knew it for
9 when the discovery rule tolled, although you might be quite
10 right that it isn't dispositive on a 93A claim.

11 In addition, knowledge is quite relevant to
12 reasonable reliance, especially in the world of Class 3. So
13 I will take whatever I learn in the trial in November, and I
14 will use it in dealing with the Class 3.

15 Class 2 is more of a statutory kind of claim,
16 although I still have the intent to deceive, and that
17 intent-to-deceive knowledge has some relevance as to whether
18 or not there was an intent to deceive. So knowledge is
19 relevant, but it's not dispositive.

20 MR. MONTGOMERY: Your Honor, we apologize that your
21 Honor did not receive our paper earlier. I think our concept
22 about how to proceed in November is to focus, in order to
23 avoid any overlap with Class 1, on the conduct of the TPPs
24 and the context in which they were operating during the class
25 period, for your Honor to take all of the evidence that the

1 parties would present with respect to that scope. And at
2 some point, of course, you're going to have to determine the
3 issues to which that evidence is relevant. We certainly have
4 a disagreement about the relevance of this evidence, but
5 certainly it is relevant to the statute of limitations issue,
6 and that's why we focused on statute of limitations.

7 THE COURT: Right.

8 MR. MONTGOMERY: But we think it's broader.

9 THE COURT: I think that I want to jump start this
10 for lots of reasons. One is, this litigation is too slow.
11 I'm starting myself to feel bogged under by it without an end
12 in sight. I think, to the extent that I hold a trial, I will
13 get a handle on the issues in a way that will make me a
14 better trial judge for the actual jury trial. Two, I think
15 it will facilitate people taking a good look at whether
16 settlement is in their best interests; and, three, I can sort
17 of figure out as I'm going some of the expert issues without
18 having to have a major new Daubert hearing. I was thinking
19 of possibly -- are you going to be calling your witness in
20 any event for that --

21 MR. BERMAN: Our expert witness?

22 THE COURT: Yes.

23 MR. BERMAN: Yes, we are, your Honor.

24 THE COURT: So one thought I have is, since you're
25 paying him by the day anyway, I'm sort of assuming, I would

1 see him some of the afternoons on the Track 3 expectation
2 kind of theory.

3 MR. BERMAN: Correct.

4 THE COURT: Does that make sense?

5 MR. BERMAN: We were going to suggest that you can
6 do any Daubert-ing while you're listening and they're
7 cross-examining at that hearing.

8 THE COURT: So I'm going to do Track 1, Class 2, in
9 November.

10 Now, I don't know what plaintiff is thinking about
11 when you're talking about -- what was it, 20 hours a side for
12 a 93A? That was what you were talking about?

13 MR. BERMAN: Well, what we think we need to do --

14 THE COURT: You think you're going to do a
15 two-month trial?

16 MR. BERMAN: No, we don't. We think we need
17 roughly five to seven days --

18 THE COURT: Three and a half hours a day.

19 MR. BERMAN: -- to get in everything we need to get
20 in on knowledge.

21 THE COURT: No, no, no, this is the whole -- catch
22 this -- the whole. It's not just knowledge. You're going to
23 prove your case, if you can.

24 MR. BERMAN: Correct.

25 THE COURT: So I don't know why it's just

1 knowledge. You think you can do seven trial days to try
2 your -- so we'll do -- we'll have a three-week trial.

3 MR. BERMAN: Correct. We can get our liability
4 case out in five to seven trial days.

5 THE COURT: But what about damages?

6 MR. BERMAN: And damages.

7 THE COURT: Okay, so seven trial days.

8 And what do you think you need?

9 MR. MONTGOMERY: Your Honor, if you're talking
10 about trying the entire case on Class 2 and Class 3 --

11 THE COURT: No, just Class 2.

12 MR. MONTGOMERY: Just Class 2, and then you're
13 talking about doing Daubert --

14 THE COURT: And there may be some overlap that I'll
15 just, you know, import into a Class 3. I'm assuming a fair
16 amount will --

17 MR. MONTGOMERY: Yes, but to just talk about
18 Class 2 and Class 3 together for a second, and just starting
19 with statute of limitations but extending to other issues,
20 we've got the same class representatives, the same kinds of
21 issues, the same conduct focusing on the TPP part of the
22 story. So it's the same for Class 2 and Class 3 until you
23 get to the edges. It's exactly the same.

24 THE COURT: Well, the edges, though, are the really
25 hard economic issues because one's a statutory claim and

1 one's sort of more of a, was there an unfair or deceptive
2 practice that somehow inflated the price in a way the TPPs
3 couldn't have known? So you may think it's identical or not.
4 I haven't thought it through --

5 MR. MONTGOMERY: We do, and I know we need to have
6 more discussion, and this is not the time to do it.

7 THE COURT: You need to have more discussion about
8 it, but, in any event, damages will vary dramatically.

9 MR. MONTGOMERY: Damages will vary.

10 THE COURT: Okay, so it's possible liability is the
11 same. I really haven't given it any thought, so. . . I'd be
12 willing to consider Track 2 and 3, but I want the whole
13 thing. I want people to really focus on this. How many
14 defendants are going to be in Track 1, four or five?

15 MR. BERMAN: Just four, your Honor.

16 MR. MONTGOMERY: No. In Track 1 there are three.
17 Oh, excuse me, Class 1 is three. Track 1 is four. Excuse
18 me.

19 MR. BERMAN: Four, and the fifth will -- we're
20 almost there. Next week.

21 THE COURT: The check's in the mail?

22 MR. SOBOL: Yes.

23 MR. BERMAN: Next week.

24 MR. SOBOL: The check's in the mail.

25 THE COURT: So that's where we'll go on it in

1 November. But let's assume for a minute you're right, that
2 it ends up being both classes and I can maybe do the Daubert
3 hearing sort of simultaneously with the bench trial so that
4 we're not wasting additional time, how much time will it
5 take?

6 MR. MONTGOMERY: Yes, I mean, this here is a lot
7 more complicated, your Honor, because if we're not talking
8 any longer as we were a month ago about the TPPs' conduct,
9 that evidence, and we're talking about the individual conduct
10 of each of four companies --

11 THE COURT: Right.

12 MR. MONTGOMERY: -- that we haven't thought about.
13 I think we need to confer. We've got four separate cases.

14 THE COURT: I do, I agree. That's why I'm asking
15 this.

16 MR. MONTGOMERY: And so I think I need to confer
17 and we need to talk about that. We can do that right now,
18 but that's a --

19 THE COURT: So you can prove against four separate
20 defendants in seven days?

21 MR. BERMAN: Yes, your Honor. We planned it out.
22 We've been anticipating this.

23 THE COURT: Okay.

24 MR. MONTGOMERY: May we have a moment?

25 THE COURT: Yes. You know, you don't have to do

1 this on the fly. I mean, it's --

2 MR. MONTGOMERY: We think it's a long time. I
3 mean --

4 THE COURT: Well, I'm not going to probably give
5 you everything you want because in a bench trial, I can play
6 with different ideas, like you can submit the direct by
7 affidavit, and then we can do cross, or you can do the direct
8 by affidavit and then do maybe an hour or two just to sort of
9 bring me along, if you will, to highlight your big points and
10 then have cross. There's so much we can do, and I know this
11 case at this point, so I don't need background on the
12 industry so much. It's always good to refresh my
13 recollection because there's the WACs and the MACs and, you
14 know, all the different acronyms, but basically I have some
15 sense of how it works, so I think it's not going to be so
16 hard. But what date did we have it set for?

17 MR. BERMAN: You just had a month. You didn't give
18 us a date for the November trial.

19 THE CLERK: Yes. It's November 6.

20 MR. EDWARDS: Originally, your Honor, you had
21 November 8 as a potential trial date for BMS when we were
22 doing Class 1 trials first.

23 MR. MONTGOMERY: But in your recent order, you
24 simply said "in November."

25 THE COURT: All right, so fair enough. Okay, so

1 it's November 6? Okay. So I think that's right. As soon as
2 I took Mr. Wise out of the hot seat as the only guy up there,
3 never did I see a happier man as he walked out of the last
4 hearing. Hopefully you're going to have to prove against
5 separate defendants, so it is a bigger case.

6 MR. MONTGOMERY: You know, another issue I just
7 would like to mention, if your Honor is going to do a
8 proceeding that focuses on the defendants' conduct, it is
9 important, I think, you understand that that same evidence is
10 then going to be presented in the individual company cases on
11 Class 1 beginning in March.

12 THE COURT: A lot of it will be.

13 MR. MONTGOMERY: It will be exactly the same
14 evidence, so there is some inefficiency.

15 THE COURT: There's overlap, I understand that, but
16 I just can't wait, and then something else will happen, and
17 then something else will happen. I need some forward
18 momentum on this case. As far as I was concerned, September
19 was where I had blocked off huge amounts of time and staffed
20 up and was ready to go, and then this issue happened with
21 Medicare and with the plaintiffs assuming I'd go
22 publication. That could happen again with another issue.
23 What if the Medicare machines break down or there's another
24 hurricane and then we get bumped again? Things happen that I
25 can't control. But I can control 93A and my schedule, your

1 schedules, short of a national emergency, so I plan on doing
2 this.

3 Now, to the extent I do this, does the United
4 States want to be part of this?

5 MR. GOBENA: Your Honor, we've only intervened,
6 obviously, against Abbott labs and Hospira, so I don't
7 believe they're one of the defendants in that.

8 THE COURT: No, but I sure could use some amicus
9 help on some of these issues.

10 MR. GOBENA: If your Honor would like that, we'd be
11 more than happy to provide amicus briefing on any issues that
12 your Honor would like.

13 THE COURT: So that's a good thought. On
14 individual -- what's coming up obviously, is, will people
15 from the Center for Medicare and Medicaid Services be
16 subpoenaed as part of the trial?

17 MR. EDWARDS: No.

18 MR. BERMAN: Not from us.

19 MR. MONTGOMERY: We don't know.

20 THE COURT: Okay. So one thing, you could work
21 together with them so -- Toohy regulations, is that it? Is
22 that the name of those regulations that you don't get anyone
23 unless you jump through three hurdles --

24 MR. HENDERSON: That's the name of it.

25 THE COURT: -- and do a backward flip, right? You

1 have to decide sooner rather than later if you want a
2 government witness. The issue that might be worthwhile,
3 which I cannot rule on motions for summary judgment till
4 class notice goes out, a problem, at least for -- so, as I
5 understand it, the motions for summary judgment are just
6 sitting there on what AWP means, if you would like to submit
7 an amicus as a statutory matter.

8 MR. GOBENA: You're asking the United States, your
9 Honor?

10 THE COURT: Yes.

11 MR. GOBENA: Yes, I mean, if your Honor would like
12 that, we can do that.

13 THE COURT: Thank you. So do I need my own
14 expert? You all know this case at this point better than I
15 do. Is there anything that's going to be so hard -- the one
16 thing I'm worrying about is not the basic case; I think I can
17 understand it as well as the next person. It's assessing the
18 Daubert challenge. We've let go our independent expert, and
19 the question is, on the expectation theory, which is a novel
20 one, and I understand it's derived from the antitrust area,
21 should I get somebody?

22 MR. MONTGOMERY: Your Honor, if you think it would
23 be helpful, we certainly wouldn't disagree that it may. And
24 while we let Professor Byrne go, I think there's still the
25 reservation that you have to ask him if he's available again.

1 THE COURT: I talked with him, and I'm just trying
2 to remember. I think he had a few offers to do things with
3 the industry, and it was going to conflict him out.

4 MR. CAVANAUGH: Your Honor, we took an informal
5 poll. We don't think any of the companies have retained him
6 at this point.

7 THE COURT: I could give him a call.

8 MR. BERMAN: We were asked, if you recall, to stop
9 retaining him because he wanted to go work for the industry.

10 THE COURT: But maybe he never did, but I think he
11 had an -- I can't remember what it was. I think -- you know,
12 it's funny, you think you remember and you don't -- I think
13 he had an opportunity to go work with somebody in the
14 industry, and he wasn't going to take it if I definitely
15 needed him, and I told him at that stage I wasn't sure.

16 MR. BERMAN: But our concern is that it may not be
17 these four but it may be three others in the AWP case that --

18 THE COURT: Well, I'll ask. I'll ask. And if not,
19 I'll try and find somebody else. Do you have somebody else
20 that you all agreed upon? Was there a runner-up when we put
21 him in the saddle?

22 MR. CAVANAUGH: No.

23 MR. MONTGOMERY: No. They suggested
24 Professor Byrne, and we accepted.

25 MR. SOBOL: Can we have a moment, your Honor?

1 THE COURT: Yes.

2 (Discussion off the record amongst plaintiffs'
3 counsel.)

4 MR. SOBOL: The concern, your Honor, that the
5 plaintiffs would have regarding either Professor Byrne or
6 some other independent expert before you would be a vehicle
7 by which any of the parties could at least question the
8 expert if the expert was going down a trail which they,
9 frankly, thought was incorrect.

10 THE COURT: I think that's actually helpful.

11 MR. SOBOL: And that would be an important
12 procedural safeguard to make sure that --

13 THE COURT: So we're at the trial stage, not the
14 class cert stage.

15 MR. SOBOL: Sure.

16 THE COURT: I think that's totally fair, I agree.
17 Yes, that makes sense because even somebody who's neutral, I
18 mean, it's a difference of expert opinion. It would
19 highlight, at least, the fair areas of disagreement. So if
20 he can't do it, I have actually one other person partly in
21 mind, although I haven't asked him so I'm reluctant to
22 float --

23 MR. CAVANAUGH: Don't tell us.

24 THE COURT: -- that I might call, and if he's
25 available, then float the name, but I'll start with

1 Professor Byrne.

2 Okay, so proposed findings of fact and law, I don't
3 think I need a pretrial memo. I don't have the room for all
4 the memos that I've received in my office, so I think what
5 we're better off doing is a brief set of proposed findings of
6 fact and law just to give me a heads-up about where you're
7 going, and then it can be supplemented afterwards. Does that
8 make some sense to all of you? I'm talking about, you know,
9 20, 25 pages for proposed findings. We could do it the way,
10 actually, you've done it in the past; maybe 25 pages sort of
11 on any common industrywide issues and maybe -- does it make
12 sense to do 15 for each company? I'm going to be getting
13 very company-specific. I mean, at this point, I have to be
14 quite candid, I haven't so much except for maybe a drug here
15 or a drug there, and I'm assuming that it's going to have to
16 be very specific per company.

17 MR. CAVANAUGH: It will be.

18 MR. MONTGOMERY: I think that would be easy for all
19 of us to do, your Honor. I mean, we do have summary judgment
20 papers in front of you. If it's more efficient for you to
21 see this shorter form --

22 THE COURT: Would that be -- I mean, my concern is,
23 as soon as I wait until after the trial to get proposed
24 findings of fact, you will all ask for a month.

25 MR. MONTGOMERY: We're fine --

1 THE COURT: And then you ask for a continuance.

2 MR. MONTGOMERY: We're fine submitting proposed
3 findings beforehand. I'm just reminding your Honor that
4 there are summary judgment papers which --

5 THE COURT: Do you all want to rely on that? That
6 makes sense.

7 MR. BERMAN: No. We would like to submit proposed
8 findings.

9 THE COURT: Well, here's the issue with doing it
10 afterwards: I forget, the problem is. I'm on to seventeen
11 other things. I've got, believe it or not, two other MDLs.
12 I've got a lot of criminal cases. So I'll forget. So when
13 you ask for a month, and then you'll ask for a month
14 continuance, and then you want to reply to one another, and
15 now by the time I get to it, it's four or five months out,
16 and I've forgotten. So I think we're really much better off
17 with things in advance. And if you think the summary
18 judgment motions, I can use that, that would be great.

19 MR. BERMAN: We need to first put in findings that
20 focus more on the 93A issues and all our evidence related to
21 that than we did in the summary judgment.

22 THE COURT: All right, fair enough. Really just so
23 you don't all have to coordinate, do you want to each do a
24 20-page memo, that's it? I'll let you supplement
25 afterwards, 20 pages of proposed findings of fact per

1 defendant, because it's going to be very defendant-specific,
2 and --

3 MR. MONTGOMERY: Do you want common?

4 THE COURT: If you do. Otherwise I could just rely
5 on the summary judgment. The common stuff, I think I know
6 what you're going to say. Whether you prove it up, I don't
7 know, but I think I know the case.

8 MR. MONTGOMERY: When would you like it?

9 THE COURT: I don't know. How about a week
10 beforehand? Does that seem fair enough?

11 MR. CAVANAUGH: That's fine.

12 THE COURT: And you just told me this, but when was
13 the opt-out time for the third-party payors?

14 MR. NOTARGIACOMO: October 1, your Honor.

15 THE COURT: So if I were to rule on the motion for
16 summary judgment, it would probably have to be sometime in
17 October, if I did. I may just move it all into the bench
18 trial, depending on how it goes.

19 Is that all we need to deal with?

20 MR. BERMAN: Could I just ask -- and maybe everyone
21 in Boston knows this, but I don't -- what days of the week
22 you're going to hold court and the what the times will be?

23 THE COURT: In general, we go from 9:00 to 1:00
24 with a half an hour break at 11:00.

25 MR. EDWARDS: Five days?

1 THE COURT: Five days a week.

2 MR. EDWARDS: Your Honor, I assume we're going to
3 have some exchange of witness lists and exhibits?

4 THE COURT: Yes, we'll send out a little pretrial
5 order in general, yes, and premarked exhibits, and I'll want
6 a set of exhibits for me and a set of exhibits for my law
7 clerks. And I will guarantee you that if you start giving me
8 18 boxes a side, I won't look at it. I won't look at
9 anything that's not flagged for me at the trial so I can put
10 a sticky on it and underline it because I'm just not going to
11 sit and read huge boxes of documents. So it would be very
12 useful to have them here, and you'll turn me to such and such
13 a page, and I will underline it, asterisk it and put a flag
14 on it. But I'm not going to just sit and randomly read
15 exhibits. It's not worth it just for an appellate record.

16 So, you know, we can just do it right now. A week
17 beforehand you'll get me -- is that acceptable for a witness
18 list, or do you want to know it further in advance than
19 that? Two weeks in advance?

20 MR. EDWARDS: Yes, I would think further in
21 advance, your Honor, so we can prepare for cross-examination.

22 THE COURT: All right, on both sides. So two weeks
23 in advance, witness lists, premarked exhibits, and share them
24 with one another; any motions in limine, although with a
25 bench trial, I'll tend to just go as we go. And the key

1 unanswered question, absolutely essential, is: Do you agree
2 that we should do 2 and 3 at the same time?

3 MR. BERMAN: No. We think, given the breadth of
4 the evidence that you're going to hear in 2, we have to prove
5 our case against each person, defendant, we should just get
6 one clean shot done; and that by doing 2, we're going to have
7 laid a foundation for 1 and 3 later on.

8 THE COURT: So what is the increment -- other
9 than -- damages is obviously key, that whole expectation
10 theory, but other than that, what would be different?

11 MR. BERMAN: Testimony about how people were
12 looking at AWP used in the non-Medicare context. There's
13 that whole other umbrella of, you know, they're going to say
14 there were negotiations; we're going to say there were no
15 negotiations. They're going to say physicians had market
16 power to change it; we're going to say that they didn't.
17 None of that is in Class 2 because they had to pay per
18 statute.

19 THE COURT: Well, what if we were to just make it
20 in a Class 2, but I would take everything from Class 2? In
21 other words, I wouldn't start again from scratch.

22 MR. BERMAN: That would be fine with us as well.

23 THE COURT: And we could set something maybe in
24 January -- well, we may all be dead by then, this is such a
25 huge effort. And you'll get me if you think I should do it

1 all at once, and then maybe you'd explain why you think it's
2 appropriate within the next week or two? Does that make
3 sense, a couple of weeks? And you'll tell me why it isn't,
4 and then we'll have plenty of time to resolve it.

5 MR. MONTGOMERY: Thank you.

6 THE COURT: But if we move beyond that, even if I
7 only do 2, I would be planning on doing 3 pretty fast right
8 afterwards. And also, if you could give me some really fair
9 sense of how long you think it would take and the difference
10 between 2 and 3, would it make a difference, that would be
11 really useful.

12 MR. EDWARDS: Your Honor, at the risk of belaboring
13 the issue, would it make sense for plaintiffs to provide
14 witness lists and exhibit lists first so that we're not
15 passing like ships in the night if we do it simultaneously?

16 MR. BERMAN: It should be mutual, your Honor. We
17 have a lot of work to do, and to make us give it to them
18 earlier is a lot.

19 THE COURT: But it does make some sense. So three
20 weeks in advance of the trial you do it. Two weeks in
21 advance of the trial you do it, and then you can supplement,
22 as long as --

23 MR. BERMAN: That's fair.

24 THE COURT: Okay, to meet head on what they're
25 going to do, okay? And then my --

1 MR. SOBOL: Witnesses and exhibits, your Honor?

2 THE COURT: Yes. And my sense is, for people out
3 of town, we're certainly not going to do it the Wednesday
4 before Thanksgiving so you can get out of here by Tuesday,
5 and I'll stop the week before Christmas so people can be home
6 for Christmas parties and the like. So I've got to assume
7 we're going to be done before Christmas. At least I'll be
8 very reluctant to have a trial go beyond that, let's put it
9 that way. So that would leave us what, six weeks? This is
10 probably only going to be a month anyway. I doubt I'm going
11 to let it go a full six weeks. So are we all set?

12 MR. DALY: Your Honor, I wanted to address the
13 amicus point that your Honor raised, speaking for Abbott and
14 Hospira. The federal government, the Department of Justice,
15 CMS, they are now in this case. They are advocates, they are
16 litigants. And Abbott, for one, would object to an amicus
17 brief being filed by an advocate in a matter that's before
18 your Honor. For example, we have a motion to dismiss that's
19 pending that your Honor will be looking at in due course, and
20 we would object to the United States being treated as an
21 amicus on issues that will be litigated in this case with
22 them as a party.

23 THE COURT: I understand, but a lot of the -- and I
24 will take it with that weight that they're now in it. That
25 having been said, it's a statutory issue and they're the

1 agency. I'm assuming they're going to represent CMS in this,
2 right?

3 MR. GOBENA: They're our client, your Honor.

4 THE COURT: They're your client? So I would like
5 to know what CMS's position is.

6 MR. GOBENA: Your Honor, a procedural matter
7 related to that. When would you like any briefing on this
8 issue? I mean, I understand you have a trial coming up.

9 THE COURT: I'm not here to destroy your family
10 vacation. When could you do it?

11 MR. GOBENA: You know, I think I'd probably need a
12 few weeks.

13 THE COURT: You're getting a whisper from over
14 here.

15 MR. GOBENA: Your Honor, if we could have it by
16 September 15, the second week in September, if everything's
17 provided, that would be helpful for us.

18 THE COURT: September 15.

19 MR. GOBENA: Is that too late for your Honor?

20 THE COURT: Okay. But it can't be an extension
21 because the truth is, if I'm going to rule on it, the motion
22 for summary judgment, I can't rule on it until after the
23 opt-out period, which is only two weeks later. However, the
24 trial is looming. I'm not sure I can get out a decision -- I
25 may merge it all into the bench trial, but it can't be any

1 later than that. So I know you have a thousand hoops to jump
2 through down there, but I'll need it.

3 And let me ask you this: If they need some witness
4 from the Center for Medi -- either side decides to call
5 someone, are you the person they should get in touch with to
6 sort of jump any of those hurdles?

7 MR. GOBENA: Either contact myself or
8 AUSA Henderson.

9 MR. DeMARCO: Your Honor, on behalf of the
10 Track 2s --

11 THE COURT: Yes, I saw you sitting back there
12 silently.

13 MR. DeMARCO: Thank you. Good afternoon, your
14 Honor.

15 THE COURT: Good afternoon. Welcome back.

16 MR. DeMARCO: If the Track 1s are finished, we just
17 wanted to have a few minutes to address a couple of lingering
18 Track 2 issues, in light of the upcoming class cert hearing
19 next month.

20 THE COURT: Okay. I haven't read it yet.

21 MR. DeMARCO: That's fine. We don't want to cut
22 into their time.

23 THE COURT: No, they're done.

24 MR. DeMARCO: They're done. Okay, well, my
25 colleague Scott Stempel would like to raise a couple of

1 issues with respect to the class cert hearing and a couple of
2 other housekeeping matters as well.

3 MR. STEMPELL: Your Honor, just one issue with
4 respect to the class cert hearing that occurs. As you were
5 discussing the possibility of bringing in an independent
6 expert, we thought it was a terrific area when you did it to
7 consider class certification for Track 1. We've got the
8 hearing coming up. Professor Byrne specifically identified
9 some areas that were in need of further development of the
10 record, which is exactly where we focused in discovery when
11 you sent us off to do discovery; specifically, the treatment
12 of multisource drugs and private payor physician-administered
13 drugs. And we think it would be helpful to have an
14 independent expert, Professor Byrne if he's available,
15 consider the record that we've developed to shed some light
16 on any lingering questions.

17 THE COURT: On class cert?

18 MR. STEMPELL: On class cert, in continuation of
19 the role he has played, and in fact --

20 THE COURT: I'll see. I released him, so I just
21 would have to find out.

22 MR. STEMPELL: There's one housekeeping issue that
23 Abbott and Dey have asked me to raise, and that is an open
24 issue on an objection from a ruling from Magistrate Bowler.
25 It's Docket 2140. It was fully briefed back in March, and it

1 had to do with a --

2 THE COURT: The objections were briefed?

3 MR. STEMPELL: Yes, the objections were briefed.

4 Judge Bowler issued an order quashing some third-party
5 subpoenas and --

6 THE COURT: I'm sorry, I missed that, so I'm glad
7 you brought that up, so we'll get those.

8 MR. STEMPELL: And just to alert you, we believe we
9 have reached an agreement, and we'll be submitting a joint
10 scheduling order relating to Mr. Bean, who is the belatedly
11 added class rep.

12 THE COURT: Okay, thank you. And have we
13 subpoenaed CMS yet for the lists with respect to Track 2 so
14 I'm not back where I started?

15 MR. BERMAN: We're right on the verge.

16 MR. MONTGOMERY: Your Honor, with respect to the
17 amicus brief, we would like leave to respond, if there's
18 anything we need to respond to it.

19 THE COURT: Of course.

20 MR. MONTGOMERY: And in particular, we'd like to
21 address the question, at least these three gentlemen would,
22 whether it's appropriate for your Honor to rule on the
23 statutory issue in light of the pendency of the notice
24 process with respect to Class 1. I think there's a potential
25 complication there as a Rule 23 matter.

1 THE COURT: Well, I can do it with respect to TPPs,
2 and then I'm going to have to do it again with respect to
3 Class 1. And that's a legal issue, in any event. What I'm
4 trying to say is, the odds of my issuing an opinion before
5 the -- what it might mean I have to do is wait until the
6 opt-out period for Class 1.

7 MR. MONTGOMERY: And that's all I was suggesting.

8 THE COURT: But it doesn't mean I have to stop
9 doing the trial.

10 MR. MONTGOMERY: I wasn't suggesting that, your
11 Honor. It was just a matter of when you issue a ruling.

12 THE COURT: It's a good question because
13 essentially, while not technically binding on the class, as a
14 matter of law of the case -- I wouldn't be violating anything
15 by doing that, but the question is whether it's wise. Do you
16 follow me, Mr. Sobol and Mr. Berman?

17 MR. BERMAN: Yes, your Honor. And our position is
18 that since you're not ruling on a claim but you're only
19 ruling on the legal meaning of the term, that you can do that
20 before the Class 2 trial, and that it's really not --

21 THE COURT: It may be. I just haven't thought of
22 it, and it's a great point. I'll think of it. If worse
23 comes to worse -- I mean, I'm not going to spit this thing
24 out like a, my expression, an ATM ruling where you stick in
25 the card and out comes the opinion. The odds of my even

1 finishing it before the opt-out period for the Class 1s is
2 pretty low, I think, so -- okay, great, have a nice summer,
3 because I don't see you again, do I?

4 MR. BERMAN: No, your Honor.

5 THE CLERK: Court is in recess.

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C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court
Reporter, do hereby certify that the foregoing transcript,
Pages 1 through 35 inclusive, was recorded by me
stenographically at the time and place aforesaid in Civil
Action No. 01-12257-PBS, MDL No. 1456, In re: Pharmaceutical
Industry Average Wholesale Price Litigation, and thereafter
by me reduced to typewriting and is a true and accurate
record of the proceedings.

In witness whereof I have hereunto set my hand this
8th day of August, 2006.

LEE A. MARZILLI, CRR

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